

INTERNATIONAL
**Food
Additives
Council**

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October 31, 2002

National Organic Standards Board
c/o Robert Pooler
Agricultural Marketing Specialist
USDA/AMS/TM/NOP
Room 2510-So., Ag Stop 0268
P.O. Box 96456
Washington, D.C. 20090-6456

(Submitted via e-mail to: nlpetition@usda.gov)

Dear Mr. Pooler,

The International Food Additives Council (IFAC) is a U.S. based international trade organization representing companies who produce high quality substances used worldwide as food additives. The Phosphates Committee of IFAC is submitting a petition to the National Organic Standards Board for the inclusion of sodium acid pyrophosphate on the National List for the National Organic Program.

The petition was prepared according to the guidelines given in the National List Petition Process section of the National Organic Program internet website, as well as the corresponding Federal Register notice of July 13, 2000.

We believe that it is critical to add sodium acid pyrophosphate to the National List in order to provide the appropriate leavening ingredients for certified organic foods manufacturers to offer a variety of baked goods to the consumer.

If you have any questions about this petition, please contact directly the Phosphates Committee Chair: Lori L. Klopff, Ph.D., 314-674-1459.

In addition, IFAC wishes to once again point out that the food gum, Carrageenan, has been excluded from the approved gums and such appeared to be an oversight. Please see our letters of June 12, 2000, January 3, 2001 and March 23, 2001. IFAC again requests correction of this oversight. On this matter feel free to contact me at 404 252-3663.

Sincerely,

Andrew G. Ebert

Andrew G. Ebert, Ph.D.
President

AGE/jcr

cc: *Keith Jones, Program Manager, National Organic Program*
(keith.jones@usda.gov)
IFAC Phosphates Committee
IFAC Food Gums Committee

PETITION TO THE NATIONAL ORGANIC STANDARDS BOARD (NOSB) for:

Sodium Acid Pyrophosphate (SAPP)

Item A:

We are petitioning to include Sodium Pyrophosphate (SAPP) in the National List category for "Nonagricultural (nonorganic) substances allowed in or on processed products labeled as 'organic' or 'made with organic (specified ingredients)'", Section 205.605 (b).

Item B:

1. Common Name: sodium acid pyrophosphate
 Other Names: disodium pyrophosphate
 disodium dihydrogen pyrophosphate
 disodium diphosphate

2. Manufacturer's name, address, and telephone number

This petition is being submitted by the International Food Additives Council (IFAC), which is a trade association representing suppliers of food ingredients. The Phosphates Committee of IFAC is comprised of several domestic and non-domestic manufacturers of phosphates used throughout the world in food products. The information for this petition was compiled using information from the IFAC Phosphate Committee members.

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3. Intended or current use of the substance:

The intended use of SAPP for this petition is for use as a leavening acid in baked goods.

SAPP is a common food additive with FDA and USDA approved uses for many other technical functions in foods. These include:

- Use as a sequestrant, for example to sequester iron during the processing of potatoes to prevent a gray discoloration from occurring
- Use as an emulsifying agent in process cheese applications
- Use in canned tuna as an inhibitor of the formation of struvite crystals
- Use as a curing accelerator in certain processed meats to accelerate color fixing or preserve color during storage
- Use in meat and poultry products to decrease the amount of cooked out juices
- Use as a hog carcass scald agent to remove hair
- Use as a poultry carcass defeathering agent
- Use as a sequestrant in potable water treatment (approved by the National Sanitation Foundation, NSF)

4. The mode of action of this substance:

Functionality of SAPP as a leavening agent in baked goods:

Most baked goods are made with chemical leavening, other than yeast bread (which is a very time intensive procedure). Examples of chemically leavened baked goods include: waffles, pancakes, muffins, biscuits, cakes, cookies, flour tortillas, breading batters, and doughnuts. SAPP is used as an acid source to react with sodium bicarbonate (baking soda). This produces a very controlled release of the carbon dioxide (CO_2) that leavens (or raises) the baked good.

The biggest challenge in formulating a baked good is to control the release rate of the CO_2 so that it is produced at the right time during the manufacturing process. SAPP is the **only** leavening acid that provides that flexibility and control to the manufacturing process. A variety of grades of SAPP are produced and are available to food manufacturers to provide them with the specific reaction rate they need in the manufacturing process for their particular baked goods.

The controlled release of CO_2 for leavening is a critical step for baked goods. A certain amount of CO_2 is needed during mixing, but if too much CO_2 is produced too early, it will be lost during formation or depositing of the batter. If this occurs, then the baked good will not rise sufficiently during baking, and will have an undesirably low volume. In addition, if the CO_2 is produced during manufacturing steps where it is not wanted, there can be inconsistencies in product weight. Also, batter viscosity can be impacted, which will affect the ability of the manufacturer to make the product in a consistent manner. Either of these situations will result in lost product and increased cost to the manufacturer. If the CO_2 is released too late, the integrity of the baked good can be compromised (i.e., surface cracking can occur) and an undesirable appearance will result.

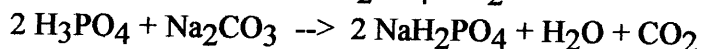
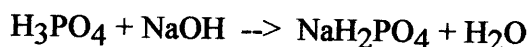
Certain baked goods, such as refrigerated doughs, can only be made with SAPP. Certain grades of SAPP release CO₂ very slowly, and are suitable for the long production cycles required by these products. Other processes for baked goods require SAPP to allow the manufacturing process to run in an efficient manner to make a product of acceptable quality and cost for the consumer.

Use Levels: The amount of CO₂ produced is controlled by the amount of sodium bicarbonate present; the exact level needed will depend on the baked good. Typically, a baked good formulation contains 1 – 3% sodium bicarbonate, and the corresponding level of SAPP is usually less than 4%. There is no advantage to an excess amount of CO₂; if anything, it would be detrimental to the quality of the product (e.g., undesirable off flavors or colors). Therefore, an excessive level of SAPP will not be used in a baked good.

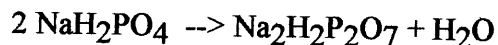
These use levels are also similar to the levels permitted in the Codex GSFA (General Standards for Food Additives). In Table One (Additives Permitted for Use Under Specified Conditions in Certain Food Categories or Individual Food Items) of this document, phosphates are permitted for use as “raising agents” in Section 07.0 Bakery Wares. The permitted use level is listed as 9300 mg/kg as P. For SAPP, which contains 27.9% P, this calculates to 3.3% SAPP permitted in this application. (This document currently being compiled by the Codex Committee on Food Additives and Contaminants of the Codex Alimentarius Commission.)

5. Manufacturing / processing procedures:

Sodium acid pyrophosphate (Na₂H₂P₂O₇) is prepared by partial neutralization of phosphoric acid with sodium hydroxide or sodium carbonate to form monosodium phosphate:



This step is followed by molecular dehydration of monosodium phosphate under controlled conditions at approximately 250°C to form SAPP:



SAPP is then milled to a powder and packaged under Good Manufacturing Practice following HACCP plans. Testing of the final product is done in accordance with the Food Chemicals Codex (FCC) monograph specifications. Also, additional quality testing may be done to ensure that the baking performance of SAPP meets the customers needs.

6. Summary of previous certification reviews of SAPP:

To our knowledge, SAPP has not previously been reviewed by the NOSB for inclusion on the National List. Sodium orthophosphates have been reviewed, and are listed in section 205.605 (b)(33) of the National List. Because sodium acid pyrophosphate is chemically different from the orthophosphates, and because it has different technical properties in food processing, it must be reviewed separately.

7. Regulatory Information:

Sodium acid pyrophosphate is a common food additive that has been available to the food industry for over 50 years. This ingredient is approved by the Food & Drug Administration (FDA) and is regulated in Title 21 Code of Federal Regulations (CFR). Section 182 Subpart B lists "Multiple Purpose GRAS Food Substances." Specifically, 21 CFR 182.1087 for SAPP states that the "substance is Generally Recognized As Safe when used in accordance with Good Manufacturing Practice." Thus, the FDA has no objection to its use in food.

SAPP is also listed in Section 182, Subpart G for Sequestrants. Specifically, 21 CFR 182.6787 lists sodium pyrophosphate to be "Generally Recognized As Safe when used in accordance with Good Manufacturing Practice."

Additionally, some food products have Standards of Identity that are also listed in Title 21 of the CFR. Below are citations for those food products for which SAPP has specific applications.

- | | |
|----------------|--|
| 21 CFR 133.169 | Pasturized process cheese. In 133.169(7)©, SAPP is listed as an approved emulsifying agent in this application. |
| 21 CFR 133.173 | Pasturized process cheese food. In 133.173(7)(e)(1), SAPP is listed as an approved emulsifying agent in this application. |
| 21 CFR 133.179 | Pasturized process cheese spread. In 133.179(7)(e), SAPP is approved as an emulsifying agent in this application. |
| 21 CFR 137.180 | Self-rising flour. SAPP is an approved acid-reacting substance. The acid is used in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts flour used. |
| 21 CFR 137.185 | Enriched Self-rising flour. SAPP is an approved acid-reacting substance. The acid is used in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts flour used. |

21 CFR 161.190 Canned tuna. "For the purpose of inhibiting the development of struvite crystals, sodium acid pyrophosphate may be added in a quantity not in excess of 0.5 percent by weight of the finished food.

The United States Department of Agriculture (USDA), which regulates meat and poultry, also allows for the use of SAPP in meat and poultry applications. Title 9 of the Code of Federal Regulations (CFR) provides a chart in section 424.21(5) of food ingredients approved for use in specific meat and poultry applications at certain usage levels. SAPP is listed in this chart for approval for:

- Curing Accelerator (used with curing agents) to accelerate color fixing or preserve color during storage. Used in frankfurters, wieners, Vienna, bologna, garlic bologna, knockwurst, and similar products. The amount is not to exceed ... 0.5% in the finished product.
- Hog scald agents to remove hair from hog carcasses. It is used at a level sufficient for purpose.
- Miscellaneous to decrease the amount of cooked out juices. It is used in most meat and poultry products at an amount not to exceed 0.5% in the total product.
- Poultry scald agents to remove feathers on poultry carcasses. It is used at a level sufficient for purpose.

8. The Chemical Abstract Service (CAS) number or other product numbers...

For sodium acid pyrophosphate:

- CAS # 7758-16-9
- International Number System (INS) Number: 450(i)
- EINECS # 231-835-0
- Monographs stating specifications for purity and safety considerations for use of SAPP in food products are published in various compendia, including:
 - Food Chemicals Codex (FCC), produced by the Food and Nutrition Board, which is a unit of the Institute of Medicine of the U.S. National Academy of Sciences.
 - Joint FAO/WHO Expert Committee on Food Additives (JECFA), a joint effort of the Food and Agriculture Organization of the U.N. and the World Health Organization
 - European Commission's Directive 96/77/EC, specifications for food additives, & update 82/02/EC in October 2002

- Japan's Specifications and Standards for Food Additives (JSFA), of the Ministry of Health and Welfare of Japan

9. Physical properties and the chemical mode of action:

Molecular formula: $\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$

Molecular weight: 221.9

Sodium acid pyrophosphate is a white, crystalline powder with no odor. The melting point is about 900°C. The pH of a 1% solution of SAPP in water is about

4. SAPP is soluble in water at the following levels:

5.0 (g/100 g H_2O) @ 0°C

12.5 (g/100 g H_2O) @ 25°C

20.0 (g/100 g H_2O) @ 50°C

As described above in section 4, SAPP reacts chemically in a leavening system with a base, such as sodium bicarbonate. This produces carbon dioxide gas, which provides the leavening, or raising, action in the baked good.

SAPP is not considered a hazardous material for transportation or disposal purposes. If exposed to the environment, SAPP would eventually hydrolyze to sodium orthophosphates, which are also approved food additives (both in the FCC and on the NOP National List). Additional toxicological information is presented in the Material Safety Data Sheet (MSDS), which is being sent with this document.

10. Safety Information:

The attached file of the Material Safety Data Sheet (MSDS) for sodium acid pyrophosphate contains the requested safety information.

The Food & Drug Administration also did a review of phosphates in 1979, in which they proposed the affirmation of phosphates as Generally Recognized as Safe (GRAS). This proposed rule can be found in the Federal Register, Vol. 44, No. 244, December 18, 1979.

11. Bibliography / Review:

Bibliography

References that discuss the use of SAPP in the food (primarily baking) industry are listed below:

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12. Petition Justification Statement:

This petition is for the inclusion on the National List of sodium acid pyrophosphate, a synthetic food additive produced from the purification and processing of natural inorganic raw materials.

SAPP is a necessary food ingredient for the commercial production of a wide range of baked goods, including waffles, pancakes, muffins, biscuits, cakes, cookies, flour tortillas, breading batters, and doughnuts. The unique controlled leavening reaction of SAPP with baking soda is essential in the baking of these food products, whether they are for the organic or the conventional consumer market.

Other leavening acids which are currently on the National List include two of the calcium phosphates listed in section 205.605(b): monobasic calcium phosphate (MCP) and dibasic calcium phosphate (DCP). MCP is a fast acting leavening agent; reaction with the baking soda in a formulation occurs rapidly and immediately. DCP-dihydrate can be used as a heat-activated leavening agent; it releases leavening acid (which can then react with the baking soda) when heated to about 140°F. The reaction rate, however, is too slow for the leavening effect needed in all but a few baked good products. Neither MCP nor DCP-dihydrate are appropriate for use in the baked goods listed above which need the controlled leavening reaction rate which is characteristic of sodium acid pyrophosphate.

Yeast could be considered an organic leavening agent that is useful in certain baking applications. In commercial baking operations, however, yeast reacts much too slowly to be considered a viable leavening agent. In such commercial baking operations, continuous production lines are often utilized in which the formulations are mixed, and then a specific amount of time is allowed (on the

production line) before the product undergoes the next step in producing the baked good (e.g., pouring into molds, baking, cooling, etc.). The only way this type of production can work consistently is to use leavening agents that react with each other in a predictable manner (reaction rate and completeness of reaction). SAPP has been found to be the only leavening acid, which can meet these needs for the portion of the food industry preparing baked goods.

As listed in section 8 of this petition, sodium acid pyrophosphate is widely recognized and approved as a food ingredient in the international community. The countries or communities that have specific approvals for use of SAPP in foods include:

- The United States of America (FDA, USDA, & FCC)
- The Canadian Dept. of Justice (Food & Drugs Act)
- The European Commission (European Food Safety Authority)
- The Ministry of Health and Welfare of Japan
- The Food Standards of Australia and New Zealand
- The United Nations' World Health Organization and Food and Agriculture Organization (JECFA - Joint FAO/WHO Expert Committee on Food Additives)

In summary, it is critical to add sodium acid pyrophosphate to the National List in order to provide the appropriate ingredients for certified organic foods manufacturers to offer a wide variety of baked goods to the consumer. As more consumers turn toward the organic foods market for their food supply, it is important to provide a variety of food products, including baked goods, that are manufactured under these organic standards. Inclusion of sodium acid pyrophosphate in the list of approved ingredients would add many products (e.g., muffins, cakes, cookies, waffles, pancakes, etc.) to the choices that the consumers of certified organic foods would have available. It would provide both an economic benefit to the manufacturers of certified organic baked goods, and would also increase the overall market for the organic products that comprise the primary ingredients in these food products.



Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: SODIUM ACID PYROPHOSPHATE
Reference Number: AST10051 Date: June 23, 2000
Chemical Family: Phosphate Salts
Chemical Name: Diphosphoric Acid, Disodium Salt
Synonyms: SAPP; Pyrophosphate Acid, Disodium Salt; Disodium Dihydrogen Pyrophosphate

Company Information:

ASTARIS LLC
622 Emerson Road - Suite 500
St. Louis, Missouri 63141

Emergency telephone: In USA call CHEMTREC: 1-800-424-9300
In Canada call CANUTEC: 1-613-996-6666

General Information: 1-800-244-6169

2. COMPOSITION/INFORMATION ON INGREDIENTS

<u>Component</u>	<u>CAS No.</u>	<u>% by weight</u>
Sodium Acid Pyrophosphate	7758-16-9	95+

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Appearance and Odor: White powder with no odor

WARNING STATEMENTS

WARNING!
CAUSES EYE AND RESPIRATORY TRACT IRRITATION
MAY CAUSE SKIN IRRITATION

POTENTIAL HEALTH EFFECTS

Likely Routes of Exposure: Skin contact and inhalation

EYE CONTACT: This product may cause pain, redness, and tearing based on toxicity tests.

SKIN CONTACT: This product may cause pain, redness, and swelling. High dust concentrations were reported to cause mild skin irritation.

INHALATION: This product causes coughing, chest pain, runny nose, and burning throat. Workers exposed to dust of this product reported moderate irritation of the nose and throat, with five of the eighteen workers reporting nasal stuffiness and nosebleeds

INGESTION: This product may cause severe nausea, vomiting, abdominal discomfort, and burning sensation based on toxicity studies.

Refer to Section 11 for toxicological information.

4. FIRST AID MEASURES

IF IN EYES OR ON SKIN, immediately flush with plenty of water. If easy to do, remove any contact lenses. Get medical attention if irritation persists. Remove contaminated clothing. Remove material from eyes, skin and clothing. Wash clothing before reuse.

IF INHALED, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen

IF SWALLOWED, do NOT induce vomiting. Rinse mouth with water, get medical attention. Contact a Poison Control Center. NEVER GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON.

5. FIRE FIGHTING MEASURES

FLASH POINT: Not combustible

HAZARDOUS PRODUCTS OF COMBUSTION: Not applicable

EXTINGUISHING MEDIA: Not applicable

UNUSUAL FIRE AND EXPLOSION HAZARDS: None known

6. ACCIDENTAL RELEASE MEASURES

In case of spill, sweep, scoop or vacuum and remove. Flush residual spill area with water.

Refer to Section 13 for disposal information and Sections 14 and 15 for reportable quantity information.

7. HANDLING AND STORAGE

HANDLING:

Avoid breathing dust.
Keep container closed.
Use only with adequate ventilation.
Avoid contact with eyes, skin and clothing.
Wash thoroughly after handling.
Do not taste or swallow

Emptied container retains product residue. Observe all labeled safeguards until container is cleaned, reconditioned, or destroyed.

STORAGE: Store in a cool, dry place to maintain product performance.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

EYE PROTECTION: Where there is significant potential for eye contact, wear chemical goggles and have eye flushing equipment available.

SKIN PROTECTION: Wear appropriate protective clothing and chemical resistant gloves to prevent skin contact. Consult the glove/clothing manufacturer to determine the appropriate type glove/clothing for a given application. Wash contaminated skin promptly. Launder contaminated clothing and clean protective equipment before reuse. Wash thoroughly after handling.

RESPIRATORY PROTECTION: Avoid breathing dust. Use NIOSH/MSHA approved respiratory protection equipment when airborne exposure is excessive. Consult the respirator manufacturer to determine appropriate type equipment for a given application. Observe respirator use limitations specified by NIOSH/MSHA or the manufacturer. Respiratory protection programs must comply with 29 C.F.R. 1910.134.

VENTILATION: Provide natural or mechanical ventilation to control exposure levels below airborne exposure limits (see below). The use of local mechanical exhaust ventilation is preferred at sources of air contamination such as open process equipment.

AIRBORNE EXPOSURE LIMITS: OSHA and ACGIH have not established specific exposure limits for this material. However, OSHA and ACGIH have established limits for particulates not otherwise classified (PNOC) which are the least stringent exposure limits applicable to dusts.

OSHA PEL
15 mg/m³ (total dust) 8-hr TWA
5 mg/m³ (respirable) 8-hr TWA

ACGIH TLV
10 mg/m³ (inhalable) 8-hr TWA
3 mg/m³ (respirable) 8-hr TWA

Components referred to herein may be regulated by specific Canadian provincial legislation. Please refer to exposure limits legislated for the province in which the substance will be used.

9. PHYSICAL AND CHEMICAL PROPERTIES

Chemical Formula:	Na ₂ H ₂ P ₂ O ₇
Appearance:	White powder
Odor:	None
pH (as a 1% solution @ 25 C):	4.2-4.9
Melting Point:	About 900 degrees C
Solubility in Water:	5.0 (g/100 g H ₂ O) @ 0 degrees C 12.5 (g/100 g H ₂ O) @ 25 degrees C 20.0 (g/100 g H ₂ O) @ 50 degrees C (g/100 g H ₂ O) @ 75 degrees C

NOTE: These physical data are typical values based on material tested but may vary from sample to sample. Typical values should not be construed as a guaranteed analysis of any specific lot or as specifications for the product.

10. STABILITY AND REACTIVITY

STABILITY: Product is stable under normal conditions of storage and handling.

MATERIALS TO AVOID: None known

HAZARDOUS DECOMPOSITION PRODUCTS: None known

HAZARDOUS POLYMERIZATION: Will not occur

11. TOXICOLOGICAL INFORMATION

The dry powder may cause foreign body irritation in some individuals. Prolonged contact with the dry powder may cause drying or chapping of the skin. Workers exposed to dust of this product reported moderate irritation of the nose and throat, with five of the eighteen workers reporting nasal stuffiness and nosebleeds. High dust concentrations were reported to cause mild eye and skin irritation.

Data from Astaris single-dose (acute) animal studies with this material are given below:

Oral - rat LD50 - 3,600 mg/kg; slightly toxic
Dermal - rabbit LD50: > 7,940 mg/kg; practically non-toxic
Eye Irritation - rabbit: 66.5/110; severely irritating
Skin Irritation - rabbit: 0.7/8.0; slightly irritating
Inhalation - LC50>0.58 mg/l, 4 hr (rat) - maximum attainable concentration

No birth defects were reported in mice, hamsters, or rabbits given sodium acid pyrophosphate during pregnancy. No adverse genetic effects were reported in standard tests using animals or bacterial and yeast cells.

12. ECOLOGICAL INFORMATION

Astaris has not conducted environmental toxicity studies with this product.

Astaris has not conducted biodegradation studies with this product since when dissolved/hydrolyzed in water it yields completely mineralized materials.

13. DISPOSAL CONSIDERATIONS

This material when discarded is not a hazardous waste as that term is defined by the Resource, Conservation and Recovery Act (RCRA), 40 CFR 261. Dry material may be landfilled or recycled in accordance with local, state and federal regulations. Consult your attorney or appropriate regulatory officials for information on such disposal.

14. TRANSPORT INFORMATION

The data provided in this section is for information only. Please apply the appropriate regulations to properly classify your shipment for transportation.

US DOT

Not hazardous for transportation

Canadian TDG

Not hazardous for transportation

15. REGULATORY INFORMATION

TSCA Inventory: Listed

DSL Inventory: Listed

WHMIS Classification: D2(B) - Materials Causing Other Toxic Effects

SARA Hazard Notification

Hazard Categories Under Title III Rules (40 CFR 370): Immediate

Section 302 Extremely Hazardous Substances: Not Applicable

Section 313 Toxic Chemical(s): Not Applicable

CERCLA Reportable Quantity: Not applicable

This product has been classified in accordance with the hazard criteria of the Canadian Controlled Products Regulation and the MSDS contains all the information required by the Canadian Controlled Products Regulation.

Refer to Section 11 for OSHA Hazardous Chemical(s) and Section 13 for RCRA classification.

16. OTHER INFORMATION

	Health	Fire	Reactivity	Additional Information
Suggested NFPA Rating	2	0	0	
Suggested HMIS Rating	2	0	0	J

Reason for revision: New Company

Supersedes MSDS dated: Not Applicable

Product Use: Food Ingredient

Astaris™ is a trademark of Astaris LLC

Although the information and recommendations set forth herein (hereinafter "Information") are presented in good faith and believed to be correct as of the date hereof, Astaris LLC makes no representations as to the completeness or accuracy thereof. Information is supplied upon the condition that the persons receiving same will make their own determination as to its suitability for their purposes prior to use. In no event will Astaris LLC be responsible for damages of any nature whatsoever resulting from the use of or reliance upon information. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER NATURE ARE MADE HEREUNDER WITH RESPECT TO INFORMATION OR THE PRODUCT TO WHICH INFORMATION REFERS